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Ortho Molecular Products Inc. 3017 Business Park Drive P.O. Box 1060 Stevens Point, WI 54481 715.342.9881 Phone 800.332.2351 715.342.9866 Fax orthomolecularproducts.com Office of Special Nutritional (HFS-450) Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835



Dear Sir/Madam:

This letter will serve as notification, pursuant to section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 101.93, that Ortho Molecular Products, Inc. is using the following claim on its label (see attached labels on page 2).

Name of Manufacturer: Ortho Molecular Products, Inc.

3017 Business Park Drive

P.O. Box 1060

Stevens Point, WI 54481

Statement Text: Muscular / Skeletal Health, Women's Health, Premium Bone Building

Dietary Ingredients: Vitamin D3 (as Cholecalciferol), Vitamin K (as Phytonadione), Folic Acid, Calcium (as Hydroxapatite, Citrimal), Phosphorus (as Chelate), Magnesium (as Buffered Amino Acid Chelate, Citrate, Aspartate), Selenium (as Amino Acid Complex), Copper (as Lysinate), Manganese (as Chelazome), Molybdenum (as Amino Acid Chelate), Ipriflavone, Strontium Citrate, Montmorillonite, Boron (as Proteinate), Natural vegetable capsules, Cranberry Juice Concentrate, Turmeric Root Extract, Ascorbyl Palmitate, Microcrystalline Cellulose, Magnesium Stearate, Silicon Dioxide.

Dietary Supplement Name: Pro Bono

As required, enclosed are two photocopies of this notification.

I certify that the information presented and contained in this notice is complete and accurate, and that Ortho Molecular Products, Inc. has substantiation that the statement is truthful and not misleading.

Sincerely,

Melissa Slager

Document Control / Training Manager

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Ortho Molecular Products

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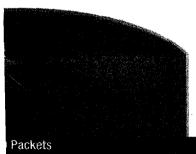


Ortho Molecular Products Inc.
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P.O. Box 1060
Stevens Point, WI 54481
715.342.9881 Phone
800.332.2351
715.342.9866 Fax
orthomolecularproducts.com

Attachment of Pro Bono Labels

PRODUCTS Efficacy Matters*

Bono[™] ne Building Pack'



racket Clear/Clear Packet Combined Facket % Daily Amount Per % Daily Amount Per Value Serving Value Serving 125% 500 IU 125% 1000 IU 325% 500 mcg 625% 1 mg 1 100% 400 mcg 10% 1000 mg 90% 100 mcg 10% 400 mg 19% 7.5 mg 1% 15 mg 143% 100 mcg 25% 400 mg 25% 500 mcg 25% 1 mg 25% 500 mcg 25% 10 mg 25% 5 mg 250% 10 mg 4 900 mg 1 000 mg 8 100 mg 1 000 mg 100% 1 000 mg 1 000 mg 1 150 mg 1 000 mg 1 150 mg 1 05 mg	Serving Size 2 Packets Servings Per Container: 30	Packets ontainer: 30	. 0				
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Horacoa 100% 400 mcg 100% 800 mcg 900 mg 90% 100 mg 10% 1000 mg 100% 1000 mg 100% 1000 mg 1000 mcg 143% 1000 mcg 143% 1000 mcg 143% 1000 mcg	Vitamin K	500 mcg	625%	500 mcg	625%	1 mg	1250%
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title, Citrimal®) ss Chelate) 7.5 mg 1% 7.5 mg 15 mg 200 mg 50% 200 mg 50% 400 mg 200 mg 50% 200 mg 100 mg 100 mcg 143% 100 mcg 25% 1 mg Complex) 5 mg 25% 500 mcg 10 mg Sinate) 500 mcg 25% 10 mg 10 mg X5 mcg 100% 75 mcg 100 mg 150 mcg Chelate) 300 mg * 300 mg * 150 mg rate 100 mg * 300 mg * 150 mg rate 100 mg * 75 mg * 150 mg rinte 75 mg * * 5 mg rinte 75 mg * 5 mg	Calcium	900 mg	%06	100 mg	10%	1000 mg	100%
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200 mg 50% 200 mg 50% 400 mg 10 kind Chelate, Citrate, Aspartate) Complex) Complex) To mcg 25% 500 mcg 25% 10 mg 250% 10 mg 250% 500 mcg 25% 10 mg 250% 10 mg 250	Phosphorus (&C)le	端 7.5 mg		7.5 mg	1%	15 mg	2%
100 mcg 143% 100 mcg 143% 200 mcg 100 mcg 143% 100 mcg 143% 100 mcg 143% 200 mcg 25% 25 mcg 25%	Magnesium	200 mg	1	200 mg	20%	400 mg	100%
0 meg 143% 100 meg 143% 200 meg 0 meg 25% 500 meg 25% 1 mg 5 mg 250% 5 mg 250% 10 mg 5 meg 100% 75 meg 100% 150 meg 00 mg * 300 mg * 600 mg 00 mg * 900 mg * 150 mg 75 mg * 75 mg * 150 mg 25 mg * 2.5 mg * 5 mg	(as Buffered Amino Acid	Chelate, Citrate,	Aspartate)				
0 mcg 25% 500 mcg 25% 1 mg 5 mg 250% 5 mg 250% 10 mg 5 mcg 100% 75 mcg 100% 150 mcg 00 mg * 300 mg * 600 mg 00 mg * 900 mg * 1500 mg 75 mg * 75 mg * 150 mg 25 mg * 2.5 mg * 5 mg	Selenium	100 mcg	143%	100 mcg	143%	200 mcg	286%
500 mcg 25% 500 mcg 25% 1 mg 5 mg 250% 5 mg 250% 10 mg 75 mcg 100% 75 mcg 100% 150 mcg ate) 300 mg * 600 mg 100 mg * 900 mg * 150 mg 75 mg 75 mg * 150 mg 75 mg * 2.5 mg * 5 mg	(as Amino Acid Com	plex)					
96) 75 mcg 100% 75 mcg 250% 10 mg Chelate) Character 100 mg Antice 75	Copper (as Lysinate)		25%		25%	1 mg	20%
x8 75 mcg 100% 75 mcg 100% 150 mcg Chelate) 300 mg * 300 mg * 600 mg trate 100 mg * 900 mg * 150 mg nrite 75 mg * 150 mg vieinate 25 mg * 5 mg	Manganese			5 mg	250%	10 mg	200%
75 mcg 100% 75 mcg 100% 150 mcg Chelate) 300 mg * 300 mg * 600 mg trate 100 mg * 900 mg * 1000 mg nite 75 mg * 75 mg * 150 mg sleinate) 2.5 mg * 5 mg	(as Chelazome®)						
* 300 mg * 60 * 900 mg * 100 * 75 mg * 15 * 2.5 mg *	Molybdenum	75 mcg		75 mcg	1	150 mcg	200%
* 300 mg * 60 * 900 mg * 100 * 75 mg * 15 * 2.5 mg *	(as Amino Acid Chel	ate)					Section 20 March 2019
* 900 mg * 100 * 75 mg * 15 * 2.5 mg *	Ipriffavone	300 mg	*	300 mg	*	600 mg	
* 75 mg * 15 * 2.5 mg *	Strontium Citrate	l	*	900 mg	*	1000 mg	*
* 2.5 mg *	Montmorillonite	75 mg		75 mg		150 mg	*
	Boron (as Proteina	ate) 2.5 mg	*	2.5 mg		5 mg	
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Other Ingredients: Natural vegetable capsules, Cranberry Juice Concentrate and Turmeric Root Extract. This product may contain one or more of the following: Asc Palmitate, Microcrystalline Cellulose, Magnesium Stearate and Silicon Dioxide. Chelazome® and Citrimal® are registered trademarks of Albion, Inc. †This statem has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Mig. by, Ortho Molecular Products, Inc. 3017 Business Park Drive Stevens Point, Wi 54481 Ortho Molecular Products.com Suggested Use: As a dietary supplement, 2 packets per day taking one Clear / White packet in the AM and one Clear / Clear packet in the PM. Maintenance: 1 packet per day alternating 1 Clear / White packet on odd days and 1 Clear / Clear packet on even days or as recommended by your health care professional. Formulated to be free of allergens derived from: Gluten, corn, egg, dairy, peanuts, artificial colors and flavors. If you are pregnant or nursing, consult your physician before taking this product. As with all dietary supplements, some individuals may not tolerate or may be allergic to the ingredients used. Please read the ingredient panel carefully prior to ingestion. Cease taking this product and consult your physician if you have negative reactions upon ingestion. Keep container tightly closed. Store at room temperature. Keep out of reach of Children. This product was sealed for your protection. Do not use if outer logoed neck seal or printed inner seal are missing or damaged.



Property Premium B

Label ID L-OMP100-350060-D



Also Excellent for:



Dietary Supplement Product #350

